

**REMARKS:**

In the Office Action dated March 18, 2010, claims 20-27 in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 20-27 remain in this application, claims 1-13 have been withdrawn, claims 14-19 have been canceled, and new claims 28 and 29 have been added to the application. Support for new claim 28 can be found throughout the application and at least on page 5, lines 33-39 of the present application. Support for new claim 29 can be found throughout the application and at least on page 4, lines 16-21, of the present application.

In the only remaining rejection, claims 20-27 were rejected under 35 USC§103(a) as unpatentable over Pierpaoli (US 4,746,674) in view of Noser (US 2002/0034485) further in view of Kondo (JP410287531A). Pierpaoli provides a method for treating the skin and/or scalp of a human subject, comprising topically administering an effective amount of a composition comprising melatonin, wherein melatonin is preferably provided in a concentration ranging from  $10^4$  to about 1% by weight. If the composition is orally administered, it is administered at an effective daily dose of about 0.1 to about 100 mg/kg. Noser is directed to a hair tonic for preventing or reducing hair loss, wherein the hair tonic comprises (a) at least one saturated or unsaturated C<sub>10</sub>-C<sub>18</sub> fatty acid or a salt thereof, and (b) at least one effective ingredient selected from the group consisting of biotin and caffeine. According to the citation, biotin increases the strength and tear resistance of hair to outside or environmental influences and strengthens the anchoring of the bottom of the hair in the scalp. Applicants point out that the main active ingredient in Noser is the C<sub>10</sub>-C<sub>18</sub> fatty acid or salt thereof. Noser indicates that

biotin and/or caffeine can also be included in the hair tonic but neither is mandatory as either one can be used in combination with the C<sub>10</sub>-C<sub>18</sub> fatty acid. Thus, one skilled in the art would not have been motivated to specifically select biotin as a mandatory component of a composition for promoting hair growth based on the teaching of Noser. In addition, Noser does not teach that biotin is effective without the C<sub>10</sub>-C<sub>18</sub> fatty acid. Since Hanada (cited in the previous office action) teaches that biotin is generally ineffective unless combined with specific active ingredients (e.g. purine compounds, pyridylurea compounds, diphenylurea compounds, pyrimidine compounds, imidazole compounds, benzoylaminourea compounds and 4-substituted aminopyrrolo [2,3-d]pyrimidine compounds), one would not assume that biotin can be used with any and all active ingredients (e.g. melatonin). Thus, Noser teaches that biotin must be used with C<sub>10</sub>-C<sub>18</sub> fatty acids to be effective. In other words, Noser teaches away from using biotin without C<sub>10</sub>-C<sub>18</sub> fatty acids. One skilled in the art would not use biotin without C<sub>10</sub>-C<sub>18</sub> fatty acids as in the present invention without the use of inadmissible hindsight. Kondo discloses a cosmetic composition for promoting hair growth, wherein the composition comprises (a) 0.00001-10% by weight of a dry extract of ginkgo biloba, and (b) a suitable carrier. Kondo does not suggest or disclose the use of biotin without C<sub>10</sub>-C<sub>18</sub> fatty acids. The claims in the present application have been amended to indicate that the only active ingredients in the composition used in the claimed invention are melatonin or a derivative thereof, ginkgo biloba and biotin. Therefore, the claims exclude the C<sub>10</sub>-C<sub>18</sub> fatty acids required by Noser. The combination of Pierpaoli and Kondo does not suggest the composition according to the present invention.

In addition, the composition according to the present invention has surprisingly been found to prevent or delay melatonin absorption which results in a longer lasting localized effect (see page 4 of the present application). New claim 29 recites this surprising result.

In summary, Noser teaches away from the use of biotin without C<sub>10</sub>-C<sub>18</sub> fatty acids and thus teaches away from the present invention. The combination of Pierpaoli, Noser and Kondo would at best result in a composition containing melatonin, biotin or caffeine, C<sub>10</sub>-C<sub>18</sub> fatty acids and ginko biloba. The present claims do not encompass such a composition as the only active ingredients in the composition according to the present claims are melatonin or a derivative thereof, biotin and ginko biloba. In view of the above discussion and claim amendments, applicants request that this rejection be withdrawn.

New claim 28 is directed to a method for promoting hair growth on a subject suffering from androgenic or diffuse alopecia. Pierpaoli is directed to the use of a melatonin containing composition for preventing or treating drug-induced or toxic alopecia. Pierpaoli explicitly points out that toxic alopecia is different from male-pattern baldness (see col. 11, lines 40-57). In addition, as discussed in the clinical study MEL-COS-AS05 filed in response to the previous Office Action, the composition according to the claimed invention has the advantage that it significantly reduces the number of patients suffering from severe seborrhea or seborrheic dermatitis (see Figures 5 and 6 of the study), with both seborrhea and seborrheic dermatitis generally being associated with hair loss. Thus, the specific composition according to the present invention

provides an unexpected technical effect which is not disclosed or suggested in the prior art documents.

Applicants respectfully submit that all of claims 20-29 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**REQUEST FOR INTERVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 18, 2010

Dear Sir:

Applicants respectfully request an interview with the Examiner if the amendments and arguments in the response filed June 18, 2010 do not put the claims in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

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